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APPLICATION NUMBER: *60/491,971*
FILING DATE: *August 04, 2003*
RELATED PCT APPLICATION NUMBER: *PCT/US04/25238*

Certified by

Jon W Dudas

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☐ *Additional inventors are being named on the ____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

SHEATH WITH CHANNEL FOR ENDOSCOPE

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 22 ☐ CD(s), Number [ ]

☒ Drawing(s) *Number of Sheets* 6 ☐ Other (specify) [ ]

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☒ Applicant claims small entity status. See 37 CFR 1.27.

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FILING FEE AMOUNT ($): $80.00

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☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: [ ]

Respectfully submitted,

SIGNATURE [signature]

Date 08/04/03

REGISTRATION NO. (if appropriate) 41,016

Docket Number: 386/03556

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SHEATH WITH CHANNEL FOR ENDOSCOPE

FIELD OF THE INVENTION

The present invention relates to sheaths for medical apparatus.

BACKGROUND OF THE INVENTION

Endoscopes are used to view internal tissue of humans, and for many other tasks. As sterilization of endoscopes is relatively difficult, disposable sheaths which cover an endoscope are used to isolate the endoscope from the patient tissue, so as to avoid time-consuming cleaning and disinfection processes. In some cases it is desired to have one or more channels run along the endoscope. These channels may be used, for example, to pass tools and fluids to the tip of the endoscope. As the sheath should completely isolate the endoscope from the human tissue, such channels are generally attached to the sheath, so that they are on an outer side of the endoscope. This, however, enlarges the cross-section of the sheath-covered endoscope being inserted into the patient. Such a larger diameter may make the insertion of the endoscope more difficult or may prevent the insertion altogether.

U.S. patent 5,025,778 to Silverstein et al., the disclosure of which is incorporated herein by reference, describes a sheath having an elastic double wall portion which is inflatable (stretchable) to form a channel after the endoscope is inserted into the patient. The 5,025,778 patent also describes an embodiment of an inflatable sheath entirely surrounding an endoscope, which is inflatable to form an annular channel. The inflating of the channel is problematic, however, especially when the endoscope is inserted to a tight tissue location. Furthermore, even if the inflating of the channel is possible, the forces involved in inflating the channel may distort the layout of the endoscope. Also, the tendency of the channel to return to its relaxed state adds significant frictional resistance to movement of devices through the channel.

SUMMARY OF THE INVENTION

An aspect of some embodiments of the present invention relates to a sheath assembly for an endoscope, which includes a foldable channel. The envelope material defining the channel is referred to herein as a sleeve. During insertion of the endoscope, the foldable channel is folded, such that its volume does not substantially add to the cross-section area of the endoscope and sheath. After insertion, the channel is unfolded so that fluid, tools and/or a working tube (referred to in the art also as a working channel) may be passed through the channel. It is noted that the unfolding may be performed by injecting the fluid, or inserting a working tube or tool or may be performed as a separate step. In some embodiments of the invention, the folded channel wall is folded in pleats during insertion. Alternatively or

additionally, the wall of the channel is wrapped on a side of the endoscope. Alternatively, the foldable channel is connected to a portion of the wall of a sheath in which the endoscope is inserted.

In some embodiments of the invention, the foldable channel automatically collapses when it is not held open, for example by a working tube running through the channel. Thus, when the channel is to be removed, the channel is automatically collapsed by removing the working tube or whatever is holding the channel open. A channel that tends to collapse when not held open is referred to herein as self-collapsible. Alternatively, the foldable channel is non-self-collapsible. The channel may be forcefully closed before removal or may be removed while in its open state.

In some embodiments of the invention, the channel is defined between two concentric sheaths. An inner sheath isolates the endoscope from the patient's tissue, while the outer sheath defines the channel. Optionally, the two concentric sheaths are partially connected. In some embodiments of the invention, the sheaths are connected along a thin longitudinal line, having the channel include substantially the entire cross-section of the outer sheath. Thus, the channel has a substantially annular shape. Alternatively, the sheaths are connected over a substantial portion of their circumference, having the channel have a limited area of the cross section of the outer sheath. In some production methods concentric sheaths are easier to produce than adjacent sheaths.

In some embodiments of the invention, the sheath assembly includes a plurality of foldable channels or one or more inflatable channels and one or more foldable channels.

In the following description and claims the term foldable channel is taken to refer to a channel whose volume can be reduced by folding the channel walls, such that the perimeter of the walls is mostly the same length in the folded state as in the open state. The terms inflatable channel and stretchable channel refer to channels that have a reducible volume due to a substantial reduction in the perimeter of the walls of the channel in the closed state. The term condensable channel refers herein to any channel that has a state in which its volume is substantially reduced.

An aspect of some embodiments of the present invention relates to a sheath assembly for an endoscope which includes at least two concentric sheaths which are partially longitudinally attached to each other. The volume between the concentric sheaths is used as a channel of the sheath assembly. Partially connecting the concentric sheaths controls the path of tools or working tubes when inserted into the channel.

Optionally, the concentric sheaths are attached to each other along at least one longitudinal line running along substantially the entire length of the sheath assembly. Alternatively, the concentric sheaths are attached only along a portion of their longitudinal length.

In some embodiments of the invention, the concentric sheaths are attached along a plurality of separate longitudinal lines. Alternatively or additionally, the concentric sheaths are connected along at least a third or even half the circumference of the concentric sheaths.

An aspect of some embodiments of the present invention relates to a sheath assembly including a condensable channel having a nozzle at its distal end. The condensable channel optionally includes a foldable channel or an inflatable channel. The nozzle is optionally used to direct a fluid passing through the channel in a specific direction, for example to wash a viewing window of the endoscope.

An aspect of some embodiments of the present invention relates to an endoscopic sheath adapted to allow insertion of a working tube into a channel defined by a condensable sheath. The working tube defines an external protrusion and the sheath includes a respective groove for receiving the protrusion, running along its length. In an exemplary embodiment of the invention, the external protrusion comprises a dovetail and the groove comprises a partially closed notch which prevents annular escape of the protrusion from the groove. Alternatively, annular escape is prevented by the tight fitting of the working tube into the relatively flexible channel. The groove may run over the entire length of the sheath or may run over a portion (e.g., a proximal portion) of the sheath.

An aspect of some embodiments of the present invention relates to a method of inserting a working tube into a channel defined by a condensable endoscopic sheath, using a guide wire running along the channel. In some embodiments of the invention, the guide wire is preinserted in the channel, for example at the time of manufacture of the sheath, so that there is no need to separately insert the guide wire into the patient. Alternatively, the guide wire is inserted into the channel after the sheath is inserted into the patient, so that the guide wire does not interfere in inserting the sheath into the patient.

In some embodiments of the invention, the sheath is inserted into a patient with a guide wire threaded through a distal end of the sheath. The ends of the guide wire extend through the proximal end of the sheath. In inserting the working tube into the flexible channel, the working tube is connected to a first end of the wire. The second end of the wire is pulled to bring the

working tube to move into the channel. Alternatively, the guide wire is anchored to a distal end of the sheath.

There is therefore provided in accordance with an embodiment of the invention, a sheath assembly for an invasive probe, comprising an internal sheath for covering a probe and a channel sleeve, coupled to the internal sheath, having a closed position in which the sleeve is folded and does not add substantially to the cross section area of the sheath assembly, and having an open position in which the sleeve is unfolded and adds to the cross section area of the sheath assembly.

Optionally, the channel sleeve is folded in the closed position in an unorganized manner. Alternatively, the channel sleeve is folded in the closed position in an organized manner. Optionally, the channel sleeve is pleated in the closed position. In some embodiments of the invention, the channel sleeve is folded over the internal sheath, in the closed position.

Optionally, the channel sleeve is included in an external sheath surrounding the internal sheath. Optionally, the channel sleeve is not attached to the internal sheath. Optionally, the sleeve and the internal sheath are coaxial. Optionally, the channel sleeve is attached to the internal sheath. Optionally, over most of the length of the sheath assembly the external sheath is not connected to the internal sheath. Alternatively, over most of the length of the sheath assembly the external sheath is connected to the internal sheath in at least one longitudinal line.

Optionally, the channel sleeve includes an internal notch adapted to receive a dovetail of a working tube. Optionally, the channel sleeve comprises an elastic material. Alternatively, the channel sleeve comprises a relatively non-elastic material. The channel sleeve is self collapsible or non-self collapsible. Optionally, the channel sleeve is deformed in a manner which prevents self-collapsing.

There is further provided in accordance with an exemplary embodiment of the invention, a method of providing an endoscopic channel, comprising inserting a probe with a sheath assembly including a folded sleeve and unfolding the sleeve while the sleeve is within the patient. Optionally, unfolding the sleeve comprises inserting a working tube or a tool into the sleeve. Optionally, unfolding the sleeve comprises dissolving an adhesive holding the sleeve folded and/or injecting a fluid into the sleeve.

There is further provided in accordance with an embodiment of the invention, a sheath assembly for a probe, comprising an internal sheath configured to isolate a probe from body fluids and an external sheath surrounding the internal sheath, the internal and external sheaths

being connected to each other over at least one longitudinal line extending over a segment of the length of the sheaths. Optionally, the internal and external sheaths are connected over at least two longitudinal lines, so as to define a plurality of separate channels between the sheaths. The internal and external sheaths are connected non-symmetrically or symmetrically.

There is further provided in accordance with an embodiment of the invention, a sheath assembly for a probe, comprising an internal sheath for covering a probe, a condensable channel sleeve having a closed position and an open position and a nozzle connected to the distal end of the condensable channel sleeve. Optionally, the condensable channel comprises a foldable and/or a stretchable channel. Optionally, the nozzle is directed in a direction substantially different from the main axis of the distal end of the condensable channel. Optionally, the sheath assembly includes a window at the distal end of the internal sheath and wherein the nozzle is directed in a direction suitable for flushing the window.

There is therefore provided in accordance with an embodiment of the invention, a sheath assembly, comprising an endoscopic condensable sleeve defining a channel, including a longitudinal notch and a working tube comprising a protrusion adapted to fit into the notch of the condensable sleeve. Optionally, the protrusion has a dovetail shape. Optionally, the condensable sleeve comprises a foldable sleeve. Optionally, the condensable sleeve comprises an inflatable sleeve.

There is further provided in accordance with an embodiment of the invention, a method of inserting a working tube into a condensable channel, comprising providing a guide wire within the condensable channel, within a patient and inserting the working tube into the channel along the guide wire. Optionally, providing the guide wire comprises providing the guide wire in the channel before the channel is inserted into the patient. Alternatively, providing the guide wire comprises providing the guide wire in the channel after the channel is inserted into the patient. Optionally, providing the guide wire comprises providing the guide wire such that both ends of the guide wire extend out of a proximal end of the channel.

Optionally, providing the guide wire comprises providing a guide wire that is anchored to a distal end of the channel. Optionally, providing the guide wire comprises providing a guide wire that is threaded through a distal end of the channel.

There is further provided in accordance with an embodiment of the invention, a sheath assembly for a probe, comprising an internal sheath configured to isolate a probe from body fluids and an external sheath surrounding the internal sheath, the internal and external sheaths being connected substantially only at a plurality of circumferential points at a distal end of the

external sheath. Optionally, the internal and external sheaths coextend at their distal ends. Alternatively, the internal sheath extends beyond the distal end of the external sheath.

BRIEF DESCRIPTION OF THE DRAWINGS

Exemplary non-limiting embodiments of the invention will be described with reference to the following description of the embodiments, in conjunction with the figures. Identical structures, elements or parts which appear in more than one figure are preferably labeled with a same or similar number in all the figures in which they appear, and in which:

Fig. 1A is a schematic side view of a sheath assembly, in accordance with an exemplary embodiment of the present invention;

Fig. 1B is a cross-sectional view of the sheath assembly of Fig. 1A, in accordance with an exemplary embodiment of the present invention;

Figs. 2A and 2B are schematic cross-sectional views of a sheath assembly, in closed and open positions, in accordance with an exemplary embodiment of the invention;

Fig. 3 is a flowchart of acts performed in using a sheath assembly, in accordance with an exemplary embodiment of the invention;

Figs. 4A and 4B are schematic cross-sectional views of a sheath assembly in closed and open positions, in accordance with another exemplary embodiment of the invention;

Fig. 5 is a schematic cross-sectional view of a sheath assembly in a closed position, in accordance with another exemplary embodiment of the invention;

Figs. 6A and 6B are side and isometric views of a sheath assembly, in accordance with an exemplary embodiment of the invention;

Fig. 7 is an end view of an endoscope sheath assembly and compatible working tube with a dovetail, in accordance with an exemplary embodiment of the invention;

Fig. 8 is a side view of a sheath assembly, in accordance with an exemplary embodiment of the invention; and

Fig. 9 is a schematic illustration of insertion of a working tube into a condensable channel, in accordance with an exemplary embodiment of the invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Figs. 1A and 1B are a schematic side view and a cross sectional view of a sheath assembly 100, in accordance with an exemplary embodiment of the present invention. Assembly 100 optionally includes an internal sheath 102 adapted to receive an endoscope and isolate the endoscope from the environment. In some embodiments of the invention, a rigid pipe section 104 is located at a proximal end of internal sheath 102, to aid insertion of the

endoscope into the sheath. A sealed window 106 at the distal end of internal sheath 102, optionally isolates the endoscope from the environment while allowing a camera or fiberoptic image bundle of the endoscope to provide images of the tissue external to sheath assembly 100.

An external sheath 108, having a larger circumference than internal sheath 102, optionally surrounds internal sheath 102. During insertion of an endoscope with sheath assembly 100 into a patient, external sheath 108 is optionally closely folded around internal sheath 102, such that the cross-sectional area of an endoscope with sheath assembly 100 is not substantially enlarged by the inclusion of external sheath 108. After sheath assembly 100 is inserted into the patient, external sheath 108 is unfolded, to form a channel 112 in the area between internal sheath 102 and external sheath 108. Channel 112 is optionally used to provide fluids to the distal end of sheath assembly 100. Alternatively or additionally, channel 112 is used for introducing accessory devices. Further alternatively or additionally, a working tube is introduced to the patient through channel 112. Optionally, the working tube is relatively rigid, so that the channel does not collapse on the working tube.

The size difference between the circumferences of internal sheath 102 and external sheath 108 is optionally chosen according to a desired size of channel 112. In an exemplary embodiment of the invention, the size of the channel 112 is chosen according to a desired impedance for fluids passing through the channel. Sheath 108 optionally comprises an elastic material, such as polyurethane or polyvinylchloride with a sufficiently large amount of added plasticizer, that can bend longitudinally around corners while the sheathed endoscope is inserted into the patient. Alternatively, the material of external sheath 108 is relatively non-elastic, e.g., Polycthyleneterephtalate (PET), polyvinylchloride with a relatively small amount of added plasticizer, or a very thin (e.g., between about 0.05-0.1 mm) layer of Teflon or Polyethylene, as relatively non-elastic materials are generally more suitable for folding and for passing tubes and/or tools through them, due to their relative stiffness. In some embodiments of the invention, the elasticity of the material is chosen as a compromise between the desire for smooth bending and the easier folding and passing of tools.

In some embodiments of the invention, sheath 108 is formed in a self-collapsible manner, such that when not held open, channel 112 closes. Alternatively, sheath 108 is formed in a non-self-collapsible manner, such that once opened channel 112 does not close unless a force to induce the collapse is applied to the channel. For example, the material of sheath 108 may be deformed in a predetermined shape, as is known in the art of stents, such that it does

not collapse after being unfolded. Optionally, sheath 108 is deformed over its entire length. Alternatively, sheath 108 is deformed in one or more locations along its length, which locations are sufficient to prevent collapse of channel 112. Further alternatively, stent-like structures are embedded within sheath 108 along its length in order to prevent collapse after it is unfolded.

Internal sheath 102 optionally comprises the same material as sheath 108 possibly allowing a simpler production procedure. Alternatively, internal sheath 102 and external sheath 108 comprise different materials. For example, internal sheath 102 may comprise a thinner or weaker material as it is less affected by the forces involved in inserting the sheath assembly to a patient. Alternatively, internal sheath 102 is relatively rigid, for example reinforced by relatively rigid rings, in order to prevent inner sheath 102 being affected when channel 112 is being used.

In some embodiments of the invention, the entire annular cross-section between internal sheath 102 and external sheath 108 forms channel 112 and is open, for example, for flow of fluids. Using an annular channel is relatively immune against blockage due to bending of sheath 108, as a bend in one direction still allows passage of fluids on the opposite side of the annular channel. Alternatively, internal sheath 102 is fastened to external sheath 108 along one or more longitudinal lines or portions. The fastening of the internal sheath 102 to external sheath 108 optionally limits the size of channel 112. Alternatively or additionally, the fastening of sheaths 102 and 108 to each other does not necessarily limit the size of channel 112, but simplifies the combined insertion of the sheaths and/or prevents distortion of the sheath assembly during insertion. The fastening of the internal sheath 102 to external sheath 108 optionally also prevents a working tube or tool passed through channel 112 from inadvertently wrapping around itself during insertion to the channel.

Alternatively to including a single channel 112, in some embodiments of the invention, channel 112 is divided along its entire length into a plurality of sub-channels. Further alternatively or additionally, channel 112 is divided into a plurality of sub-channels over only a portion of the length of sheath assembly 100. For example, when the separate sub-channels are used for leading separate working tubes, the sub-channels are optionally defined at the proximal end of the channel, while at the distal end channel 112 is not divided into sub-channels.

In an exemplary embodiment of the invention, the distal end of channel 112 is formed into a nozzle 116, or is connected at its distal end to an optional external nozzle (not shown),

which directs fluid passing through the channel in a specific direction as it exits the channel. For example, the nozzle may be directed toward window 106, so the fluid can keep window 106 clean. Alternatively, the nozzle may be directed in a specific direction which is best suited for directing fluids at tissue of the patient.

In some embodiments of the invention, nozzle 116 comprises a rigid material which during insertion to the patient is bent in front of window 106, in order not to add to the diameter of sheath assembly 100 during the insertion. Nozzle 116 is optionally kept in its bent position using an adhesive or a sticky material. In some embodiments of the invention, the adhesive is detached by injecting a fluid through channel 112. Alternatively, nozzle 116 comprises a flexible material which is folded together with external sheath 108. In some embodiments of the invention, nozzle 116 is constructed as a single piece with external sheath 108. For example, nozzle 116 may include a continuous portion of external sheath 108 slightly extending beyond window 106.

Alternatively, the distal end of channel 112 does not include a nozzle. In some embodiments of the invention, the entire cross section of channel 112 is open at the distal end. Alternatively, a portion of external sheath 108 is sealed to internal sheath 102 at the distal end of channel 112, so that fluids can exit and/or enter the channel 112 from specific portions only. Further alternatively or additionally, the distal end of channel 112 is entirely sealed, for example when channel 112 has holes along its length for dispersing liquids. In some embodiments of the invention, the distal end of channel 112 is sealed during insertion and is later punctured for use.

In some embodiments of the invention, channel 112 includes one or more holes along the length of the channel, allowing the provision of fluids from points along the length of the channel. Such holes are used, for example, for dispensing a lubricant or drug.

A proximal tube 110 optionally serves as an interface to channel 112. Optionally, when channel 112 is divided into a plurality of sub-channels, each sub-channel has a separate proximal tube. The proximal ends of external sheath 108 are optionally attached to proximal tube 110 and/or are sealed to proximal ends of internal sheath 102 or to rigid pipe 104, such that the only entrance point to channel 112 is through proximal tube 110.

Fig. 2A is a schematic cross-sectional view of sheath assembly 100 in a closed position, in accordance with an exemplary embodiment of the invention. In the embodiment of Fig. 2A, the material of external sheath 108 beyond that required to tightly surround internal sheath 102 is folded by pleating in one or more locations 202 around the cross-section of external sheath

108. In Fig. 2A, external sheath 108 is spaced from internal sheath 102, for clarity. In some embodiments of the invention, the folds included in pleating locations 202 partially overlap, such that the folds are generally parallel to the surface of internal sheath 102. Alternatively or additionally, in one or more pleating locations, the folds entirely overlap, optionally being oriented partially or entirely perpendicular to the surface of internal sheath 102.

In the exemplary embodiment of Fig. 2A, external sheath 108 is connected to internal sheath 102 along two longitudinal strips 204, forming two channels 112A and 112B. As shown, the connection of external sheath 108 to internal sheath 102 is symmetric, so as to prevent deformation of the sheath assembly while insertion of the sheathed endoscope into the patient. Alternatively, the connection of the internal and external sheaths is non-symmetric, forming channel sizes most suitable for use. Optionally, the number of pleats in each location 202 depends on the intended size of the channel 112B, in an open state. Alternatively, the number of pleating locations 202 in each channel 112 depends on the intended size of the channel. As shown, the left channel 112B is intended to be larger after opening than right channel 112A and therefore includes two pleated locations 202.

Fig. 2B is a schematic cross-sectional view of sheath assembly 100 in a closed position, in accordance with another exemplary embodiment of the invention. In the embodiment of Fig. 2B, the additional material of external sheath 108, required for channel 112, is included in a portion 212 folded over the circumference of external sheath 108. Alternatively, to the additional material of external sheath 108 being folded only in one direction, as shown in Fig. 2B, the additional material may be folded in both directions, optionally evenly. The use of a single bend, as in Fig. 2B, rather than a pleating, as in Fig. 2A, reduces the amount of bending, which may weaken external sheath 108, applied to the external sheath. Pleating, on the other hand, is more easily unfolded than a relatively large bended portion. In some embodiments of the invention, the number of folds in the pleating is chosen as a compromise between the strength of the material of external sheath 108 and the allowance of relatively easy passive unfolding.

In some embodiments of the invention, the pleating and/or folding are kept in place by an adhesive strong enough to withhold the forces involved in inserting sheath assembly 100 into the patient, but not too strong to prevent intentional opening of channel 112.

Fig. 3 is a flowchart of acts performed in using sheath assembly 100, in accordance with an exemplary embodiment of the invention. An endoscope is optionally inserted (250) into internal sheath 102. The endoscope together with sheath assembly 100 is inserted (252)

into the patient and guided to a desired position. Channel 112 is then unfolded (254) after the sheathed endoscope is in place. Channel 112 is then used (256) in performing a medical procedure. In some embodiments of the invention, after the procedure, channel 112 is collapsed (258) and the sheathed endoscope is removed (260) from the patient.

Referring in more detail to unfolding (254) channel 112, in some embodiments of the invention, the unfolding is actuated by injecting a fluid into the channel at a suitable pressure.

In some embodiments of the invention, the folds and/or pleating of the sub-channel are heat set at the time of production, so that they remain in their folded position until the folds are opened. Alternatively or additionally, suction is applied to channel 112 while the sheathed endoscope is inserted into the patient, so as to keep the channel in its closed state, while the sheathed endoscope is inserted.

Further alternatively or additionally, the folds and/or pleating of the sub-channel are held by an adhesive within channel 112 and the injected fluid is a fluid that weakens or dissolves the adhesive. For example, a water soluble adhesive may be used. Alternatively or additionally, the adhesive is sensitive to temperature and is counteracted by the temperature of the injected fluid. This alternative and others may be used both with adhesives within channel 112 and with adhesives on the outside of channel 112.

In some embodiments of the invention, the folds and/or pleating are held in place by an adhesive which wears away a predetermined time after sheath assembly 100 is taken out of its packaging. For example, the adhesive may be soluble in air. The physician is required to insert (252) the sheathed endoscope into the patient within the predetermined time and then waits the remaining time until the channel opens up on its own or is easily opened due to dissolution of the adhesive. Alternatively, the adhesive is sensitive to the conditions within the patient and dissolves within a predetermined time after the insertion of sheath assembly 100 into the patient. The adhesive may dissolve, for example, due to the body temperature of the patient and/or due to body fluids.

Alternatively or additionally, the unfolding is actuated by passing a stylet (optionally having a floppy or round tip) or a working tube through channel 112, so as to mechanically open the channel. In some embodiments of the invention, the extent to which channel 112 is opened is controlled by the physician according to the size required for the medical procedure. The opening extent is optionally determined by the size and/or shape of the stylet or working tube used to unfold the channel. The working tube or stylet may have substantially any suitable cross-sectional shape, including circular, oval, triangular and rectangular. In some

embodiments of the invention, the unfolding is performed in a plurality of steps. Optionally, a first narrow stylet is inserted to channel 112 and afterwards a wider working tube is inserted into the channel.

Further alternatively or additionally, any other unfolding method, such as any of the methods known in the art for use with angioplasty balloons, is used.

In some embodiments of the invention, external sheath 108 is folded in a manner which allows for different extents of unfolding. For example, external sheath 108 may have different areas of pleating with different closing strengths, and the extent of unfolding is determined by the force exerted by the physician.

Optionally, the folds are planned such that after the channel is unfolded channel 112 does not collapse under regular conditions within the patient. Alternatively, the channel collapses when it is not held open by a fluid or a working tube within the channel. Optionally, when it is desired to remove the sheathed endoscope from the patient, the channel is allowed to collapse, for example by removing a working tube previously inserted into the channel.

Although the unfolding (254) of the channel was mentioned as a separate act from the use (256) of the channel, in some embodiments of the invention the unfolding is performed passively as part of the use of the channel.

Referring in more detail to collapsing (258) channel 112, in some embodiments of the invention, in which channel 112 is non-self-collapsible, suction is applied to channel 112 in order to collapse the channel. Optionally, the suction is continuously applied throughout the removal of the sheathed endoscope from the patient. Alternatively, the suction is applied before the sheathed endoscope is removed and thereafter the channel remains sufficiently collapsed in order to allow its easy removal from the patient, without applying suction. Further alternatively or additionally, a cord running through channel 112 is used to pull the channel into a collapsed position. Alternatively or additionally, channel 112 collapses automatically when a working tube is removed from the channel. Further alternatively or additionally, the sheathed endoscope is removed without collapsing the channel as it is easier to remove the sheathed endoscope than to insert the sheathed endoscope.

Fig. 4A is a schematic cross-sectional view of a sheath assembly 300 in a closed position, in accordance with an exemplary embodiment of the invention. In the embodiment of Fig. 4A, a main sheath 302 is devised to receive an endoscope. An additional folded sheath portion 304 defining a channel 306 is mounted on a side of main sheath 302. In some embodiments of the invention, the width along which main sheath 302 and sheath portion 304

are connected is relatively wide (e.g., close to the diameter of channel 306). Alternatively, the width along which main sheath 302 and sheath portion 304 are connected is relatively narrow, allowing both sheaths to define round channels. In some embodiments of the invention, the channel is designed to have a thin cross-section, for example with an elliptical shape, such that a relatively large channel cross section area can be achieved, without extending too far away from the body of the endoscope.

Fig. 4B is a schematic cross-sectional view of sheath assembly 300 in an open position, in accordance with an exemplary embodiment of the invention. After the sheathed endoscope is inserted into its place in the patient, folded sheath portion 304 is unfolded to bring channel 306 into a usable size.

Fig. 5 is a schematic cross-sectional view of a sheath assembly 400 in a closed position, in accordance with another exemplary embodiment of the invention. Sheath assembly 400 includes a main sheath 302 and three side folded sheath portions 304, 404 and 406. Folded sheath portions 404 and 406 are folded over the side of main sheath 302, while folded portion 304 is pleated.

In some embodiments of the invention, the structure of the sheath defining the channel and/or of the inserted working tube aids in the unfolding of the channel.

Figs. 6A and 6B are side and isometric views of a sheath assembly 450, in accordance with an exemplary embodiment of the invention. Sheath assembly 450 comprises an internal sheath 452 for covering an endoscope, and an external sheath 454, which defines a circumferential channel. Optionally, external sheath 454 does not extend distally to the end of internal sheath 452, but rather extends up to several millimeters before the distal end of the internal sheath. This option is advantageous, for example, when channel 112 is used to infuse a lubricating fluid. Alternatively, the distal end of external sheath 454 extends up to the distal end of internal sheath 452. This alternative is used, for example, when channel 112 is used to introduce a medication to a specific anatomical area.

In some embodiments of the invention, external sheath 454 is coupled to internal sheath 452 at the distal end of the external sheath. External sheath 454 and internal sheath 452 are optionally not coupled along their length, but rather only at the distal end. The coupling at the distal end is optionally performed at a plurality of bonding points 456 around the circumference of internal sheath 452. In some embodiments of the invention, the distal end of external sheath 454 has a saw tooth shape and the bonding points 456 are at the distal tips of the triangles of the saw tooth shape. Alternatively or additionally, the bonding is performed at

points 462 between the triangles of the saw tooth shape. The coupling is optionally performed symmetrically, so as to prevent deformation of the sheath assembly while it is inserted into the patient.

In some embodiments of the invention, in use, a working tube is inserted along a side of a channel 458 defined between internal sheath 452 and external sheath 454. The attachment at bonding points 456 is optionally sufficiently strong so as not to break during insertion of sheath assembly 450 into the patient, but allows breaking of bonding points 456 by an inserted working tube. Optionally, in inserting the working tube, the tube is brought to the distal end of internal sheath 452 by breaking one or more of bonding points 456.

Sheath assembly 450 is optionally used for urology applications, in which a fluid (e.g., water 460) is injected to the patient through channel 458, while an endoscope sheathed with assembly 450 is being inserted to the patient. The use of a plurality of bonding points 456 limits external sheath 454 from folding back on itself, while allowing injection of required (possibly relatively large) amounts of fluid.

Alternatively or additionally, the portions of external sheath 454 between each two bonding points 456 have a folded state and an open state.

Fig. 7 is an end view of an endoscope sheath assembly 500, after opening, in accordance with an exemplary embodiment of the invention. Sheath assembly 500 comprises an internal sheath 502, optionally having a viewing window 504, and an external sheath 506. External sheath 506 defines a notch 510 adapted to receive a dovetail 522. After sheath assembly 500 is inserted into a patient, a working tube 520 including a dovetail 522 is inserted into a channel 516 defined between external sheath 506 and internal sheath 502. Working tube 520 is optionally inserted into channel 516 by fitting dovetail 522 into notch 510 at a proximal end of sheath assembly 500 and pushing the working tube toward the distal end of the sheath assembly. The use of dovetail 522 and corresponding notch 510 prevents working tube 520 from wrapping around internal sheath 502 while the working tube is inserted into channel 516.

Alternatively to notch 510 running up to the distal end of sheath assembly 500, notch 510 runs over a portion of the length of external sheath 506. The portion of external sheath 506 including notch 510 is optionally sufficiently long to properly guide working tube 520 into place even where external sheath 506 does not include notch 510. Alternatively, dovetail 522 does not extend over the entire length of working tube 520, but only extends over a portion, optionally a distal portion, of the working tube. Having dovetail 522 extend only over a portion

of the working tube, reduces the drag due to friction when the working tube is inserted to the channel.

In some embodiments of the invention, notch 510 is defined by a portion of external sheath 506 which is reinforced so that it does not deform in normal conditions before and/or while dovetail 522 is inserted into the notch. Alternatively, for simplicity of production, the area of external sheath 506 defining notch 510 is not reinforced. In some embodiments of the invention, dovetail 522 is produced as an extension of working tube 520 from the same materials.

Alternatively to using dovetail shaped protrusion, any other protrusion shape may be used including a simple dent which is held inside its respective notch by the tight fitting of the working tube in the channel.

Alternatively or additionally to using a protrusion and notch to lead the working tube into the channel, a guide wire may be used.

Fig. 8 is a side view of a sheath assembly 600, in accordance with an exemplary embodiment of the invention. Sheath assembly 600 optionally includes an internal sheath 602 and an external sheath 608. A distal end of external sheath 608 optionally includes a reinforced portion 612 including an aperture 610. A guide wire 604 runs through aperture 610, with both its ends extending out of a proximal end of sheath assembly 600. One of the ends of guide wire 604 is optionally connected (e.g., at manufacture or by a physician at the time of use) to a working tube 620. Guide wire 604 is optionally connected to working tube 620 using any method known in the art, such as using an adhesive, thermal bonding, insert molding or mechanical or crimping attachment.

The other end of guide wire 610 is optionally connected to a handle 622 for pulling at the guide wire. After sheath assembly 600 is inserted into a patient, a physician optionally pulls at handle 622 so that guide wire 610 pulls working tube 620 into external sheath 608. The guide wire optionally remains within external sheath 608 throughout the entire procedure. Alternatively, the guide wire is removed from the channel after working tube 620 is inserted to the channel.

Fig. 9 is a schematic illustration of insertion of a working tube 802 into a condensable channel 804 of a sheath assembly 800, in accordance with an exemplary embodiment of the invention. Sheath assembly 800 optionally includes a guide wire 806 passing through channel 804. In some embodiments of the invention, guide wire 806 is anchored to a distal end of sheath assembly 800, for example at an anchor point 810. Working tube 802 optionally

includes one or more loops 814 adapted to receive guide wire 806. Alternatively, working tube includes a small conduit through which guide wire 806 is passed. During insertion, working tube 802 is mounted on guide wire 806 and is pushed into channel 804. Using the guide wire prevents working tube 802 from tangling within channel 804. Optionally, after insertion, before the medical procedure, guide wire 806 is removed from the patient. In some embodiments of the invention, the insertion of working tube 802 to the distal end of sheath assembly 800 releases the anchoring 810 of guide wire 806. Alternatively, the guide wire is not anchored so that it is easily removed from channel 804.

Alternatively to including the guide wire in the channel when sheath assembly 800 is inserted to the patient, the guide wire is inserted to the channel after the sheath assembly is within the patient. Further alternatively, a plurality of guide wires are inserted into channel 804, allowing organized insertion of a plurality of working tubes into a single channel.

Although the embodiments of Figs. 7, 8 and 9 were described with relation to an embodiment including two concentric sheaths, the methods of inserting a working tube into a channel of a sheath assembly may be used with other sheath assemblies, such as those described above with reference to Figs. 4A, 4B and 5 or those described in above mentioned U.S. patent 5,025,778. It is further noted that the methods of Figs. 7, 8 and 9 may be implemented with foldable sheaths, inflatable sheaths (e.g., sheaths that require stretching of their wall to expand) and/or any other self-collapsible or non-self-collapsible sheaths.

Furthermore, the methods of inserting a working tube may be used for insertion of other tools through a condensable channel.

Although the above description relates to a sheath assembly for an endoscope, the sheath assemblies of the present invention may be used with any other probes, including invasive probes, such as ultrasound probes, catheters and other medical devices.

It will be appreciated that the above-described methods may be varied in many ways, including, changing the order of steps, and/or performing a plurality of steps concurrently. For example, although external sheath 108 was shown as being folded in an organized, regular form, the folding may be performed without any organization, for example by crushing the material of the external sheath. It should also be appreciated that the above described description of methods and apparatus are to be interpreted as including apparatus for carrying out the methods, and methods of using the apparatus.

The present invention has been described using non-limiting detailed descriptions of embodiments thereof that are provided by way of example and are not intended to limit the

scope of the invention. It should be understood that features and/or steps described with respect to one embodiment may be used with other embodiments and that not all embodiments of the invention have all of the features and/or steps shown in a particular figure or described with respect to one of the embodiments. Variations of embodiments described will occur to persons of the art. Furthermore, the terms "comprise," "include," "have" and their conjugates, shall mean, when used in the claims, "including but not necessarily limited to."

It is noted that some of the above described embodiments may describe the best mode contemplated by the inventors and therefore may include structure, acts or details of structures and acts that may not be essential to the invention and which are described as examples. Structure and acts described herein are replaceable by equivalents which perform the same function, even if the structure or acts are different, as known in the art. Therefore, the scope of the invention is limited only by the elements and limitations as used in the claims.

386/03556

CLAIMS

1. A sheath assembly for an invasive probe, comprising:

an internal sheath for covering a probe; and

a channel sleeve, coupled to the internal sheath, having a closed position in which the sleeve is folded and does not add substantially to the cross section area of the sheath assembly, and having an open position in which the sleeve is unfolded and adds to the cross section area of the sheath assembly.

2. A sheath assembly according to claim 1, wherein the channel sleeve is folded in the closed position in an unorganized manner.

3. A sheath assembly according to claim 1, wherein the channel sleeve is folded in the closed position in an organized manner.

4. A sheath assembly according to claim 1, wherein the channel sleeve is pleated in the closed position.

5. A sheath assembly according to claim 1, wherein the channel sleeve is folded over the internal sheath, in the closed position.

6. A sheath assembly according to claim 1, wherein the channel sleeve is included in an external sheath surrounding the internal sheath.

7. A sheath assembly according to claim 6, wherein the channel sleeve is not attached to the internal sheath.

8. A sheath assembly according to claim 1, wherein the sleeve and the internal sheath are coaxial.

9. A sheath assembly according to claim 1, wherein the channel sleeve is attached to the internal sheath.

10. A sheath assembly according to claim 1, wherein over most of the length of the sheath assembly the external sheath is not connected to the internal sheath.

11. A sheath assembly according to claim 1, wherein over most of the length of the sheath assembly the external sheath is connected to the internal sheath in at least one longitudinal line.

12. A sheath assembly according to claim 1, wherein the channel sleeve includes an internal notch adapted to receive a dovetail of a working tube.

13. A sheath assembly according to claim 1, wherein the channel sleeve comprises an elastic material.

14. A sheath assembly according to claim 1, wherein the channel sleeve comprises a relatively non-elastic material.

15. A sheath assembly according to claim 1, wherein the channel sleeve is self collapsible.

16. A sheath assembly according to claim 1, wherein the channel sleeve is non-self collapsible.

17. A sheath assembly according to claim 16, wherein the channel sleeve is deformed in a manner which prevents self-collapsing.

18. A method of providing an endoscopic channel, comprising:
inserting a probe with a sheath assembly including a folded sleeve; and
unfolding the sleeve while the sleeve is within the patient.

19. A method according to claim 18, wherein unfolding the sleeve comprises inserting a working tube or a tool into the sleeve.

20. A method according to claim 18, wherein unfolding the sleeve comprises dissolving an adhesive holding the sleeve folded.

21. A method according to claim 18, wherein unfolding the sleeve comprises injecting a fluid into the sleeve.

22. A sheath assembly for a probe, comprising:

an internal sheath configured to isolate a probe from body fluids; and

an external sheath surrounding the internal sheath, the internal and external sheaths being connected to each other over at least one longitudinal line extending over a segment of the length of the sheaths.

23. A sheath assembly according to claim 22, wherein the internal and external sheaths are connected over at least two longitudinal lines, so as to define a plurality of separate channels between the sheaths.

24. A sheath assembly according to claim 22, wherein the internal and external sheaths are connected non-symmetrically.

25. A sheath assembly according to claim 22, wherein the internal and external sheaths are connected symmetrically.

26. A sheath assembly for a probe, comprising:

an internal sheath for covering a probe;

a condensable channel sleeve having a closed position and an open position; and

a nozzle connected to the distal end of the condensable channel sleeve.

27. A sheath assembly according to claim 26, wherein the condensable channel comprises a foldable channel.

28. A sheath assembly according to claim 26, wherein the condensable channel comprises a stretchable channel.

29. A sheath assembly according to claim 26, wherein the nozzle is directed in a direction substantially different from the main axis of the distal end of the condensable channel.

30. A sheath assembly according to claim 26, comprising a window at the distal end of the internal sheath and wherein the nozzle is directed in a direction suitable for flushing the window.

31. A sheath assembly, comprising:

an endoscopic condensable sleeve defining a channel, including a longitudinal notch; and

a working tube comprising a protrusion adapted to fit into the notch of the condensable sleeve.

32. A sheath assembly according to claim 31, wherein the protrusion has a dovetail shape.

33. A sheath assembly according to claim 31, wherein the condensable sleeve comprises a foldable sleeve.

34. A sheath assembly according to claim 31, wherein the condensable sleeve comprises an inflatable sleeve.

35. A method of inserting a working tube into a condensable channel, comprising:

providing a guide wire within the condensable channel, within a patient; and

inserting the working tube into the channel along the guide wire.

36. A method according to claim 35, wherein providing the guide wire comprises providing the guide wire in the channel before the channel is inserted into the patient.

37. A method according to claim 35, wherein providing the guide wire comprises providing the guide wire in the channel after the channel is inserted into the patient.

38. A method according to claim 35, wherein providing the guide wire comprises providing the guide wire such that both ends of the guide wire extend out of a proximal end of the channel.

39. A method according to claim 35, wherein providing the guide wire comprises providing a guide wire that is anchored to a distal end of the channel.

40. A method according to claim 35, wherein providing the guide wire comprises providing a guide wire that is threaded through a distal end of the channel.

41. A sheath assembly for a probe, comprising:

an internal sheath configured to isolate a probe from body fluids; and

an external sheath surrounding the internal sheath, the internal and external sheaths being connected substantially only at a plurality of circumferential points at a distal end of the external sheath.

42. A sheath assembly according to claim 41, wherein the internal and external sheaths coextend at their distal ends.

43. A sheath assembly according to claim 41, wherein the internal sheath extends beyond the distal end of the external sheath.

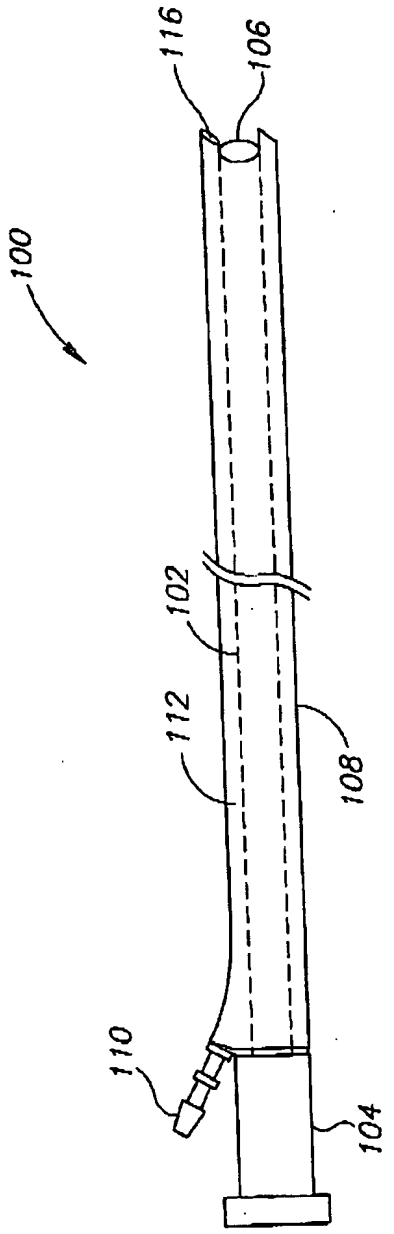


FIG.1A

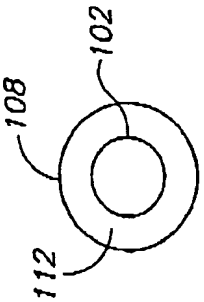


FIG.1B

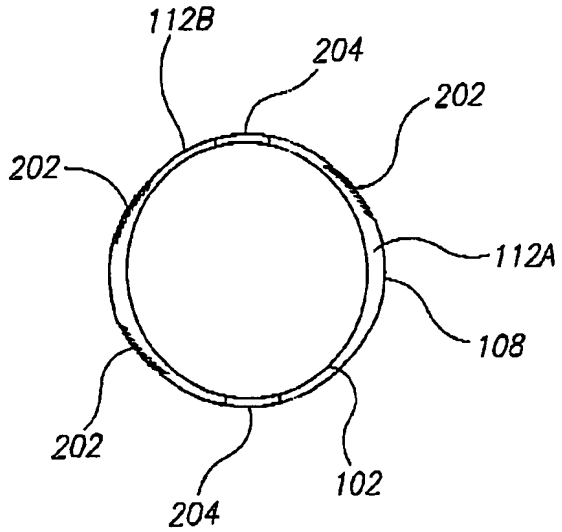


FIG.2A

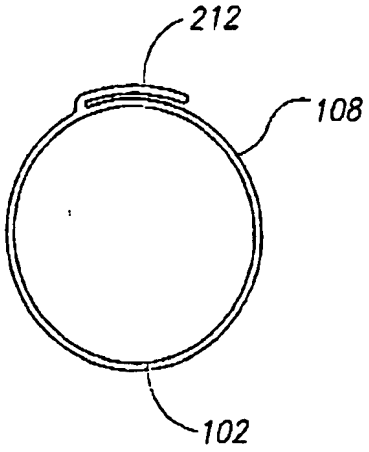


FIG.2B

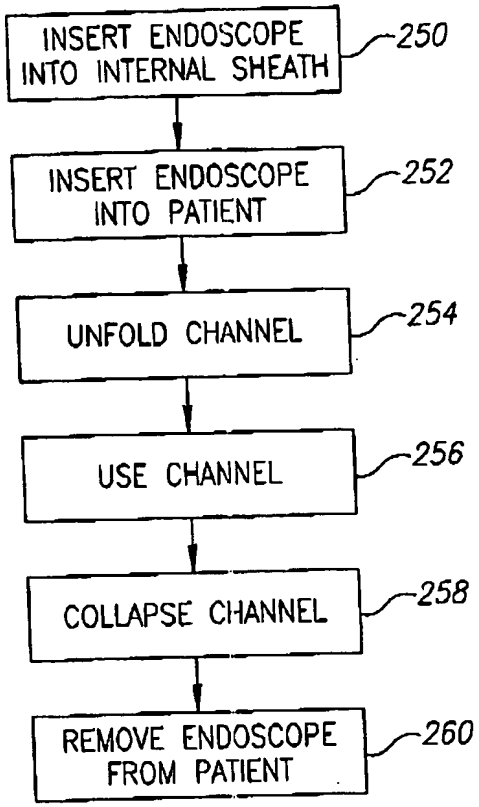


FIG.3

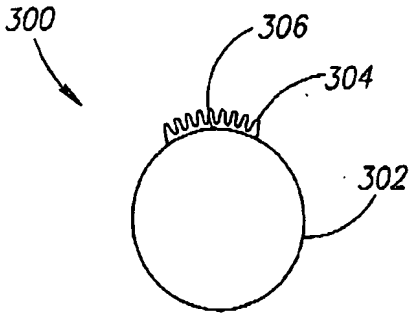


FIG.4A

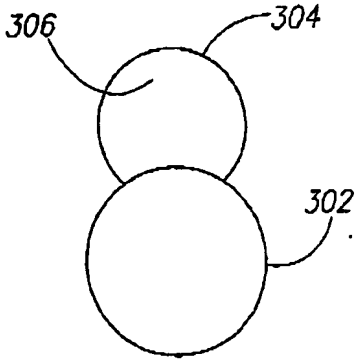


FIG.4B

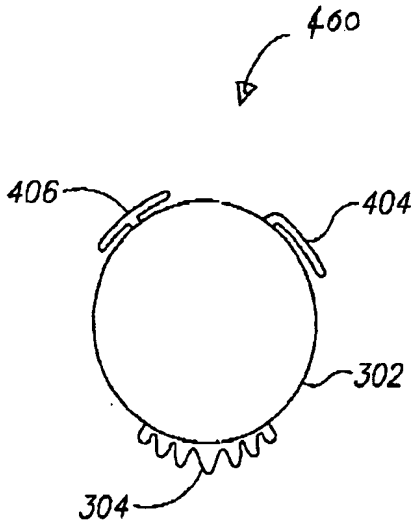


FIG.5

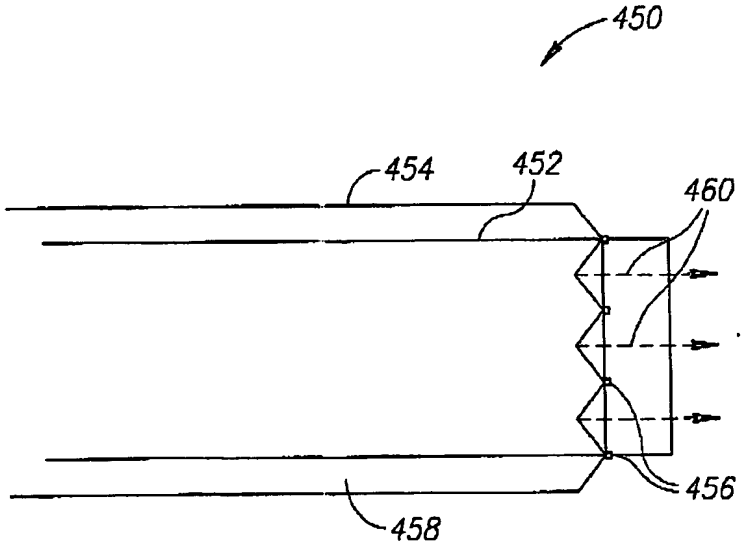


FIG.6A

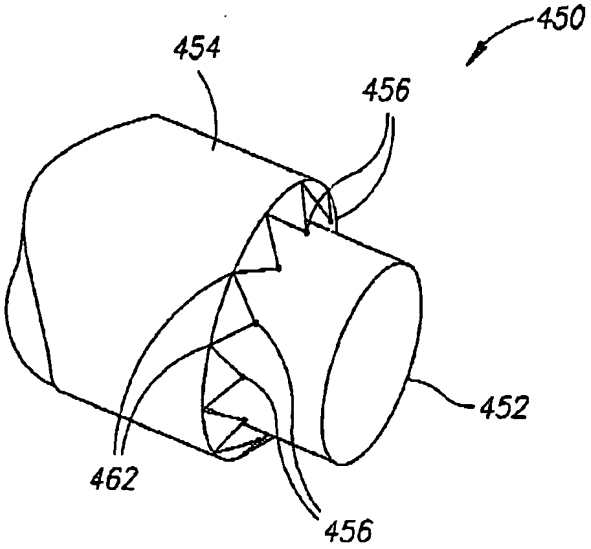


FIG.6B

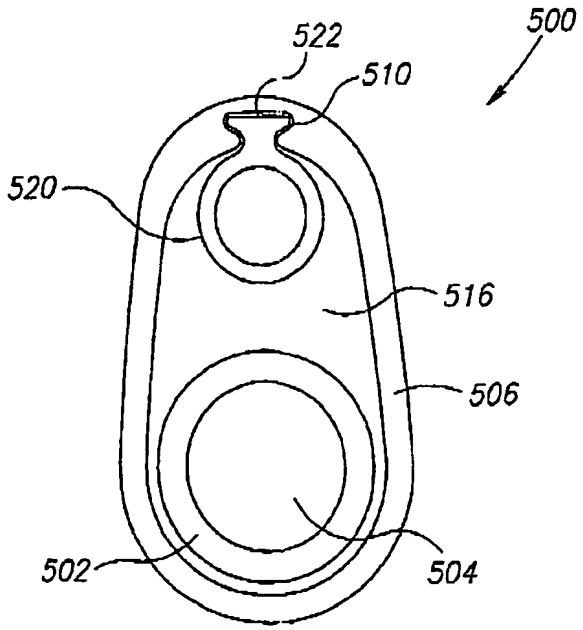
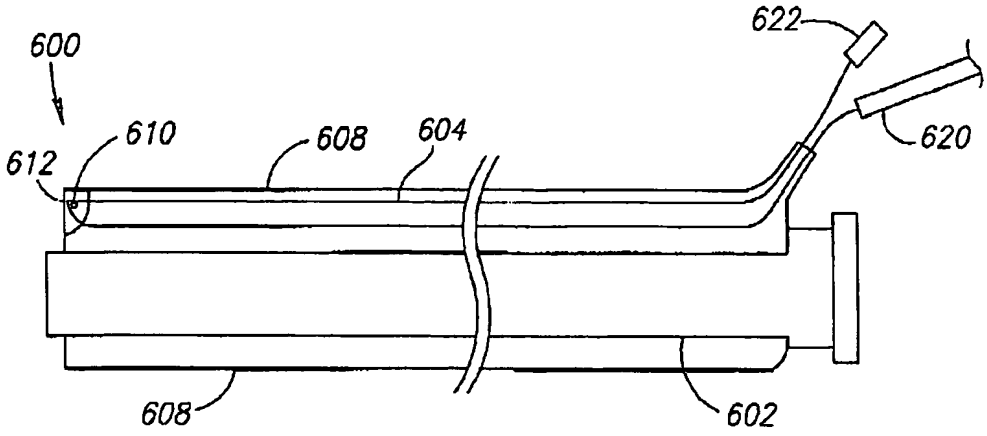


FIG.7


600
610
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622
620
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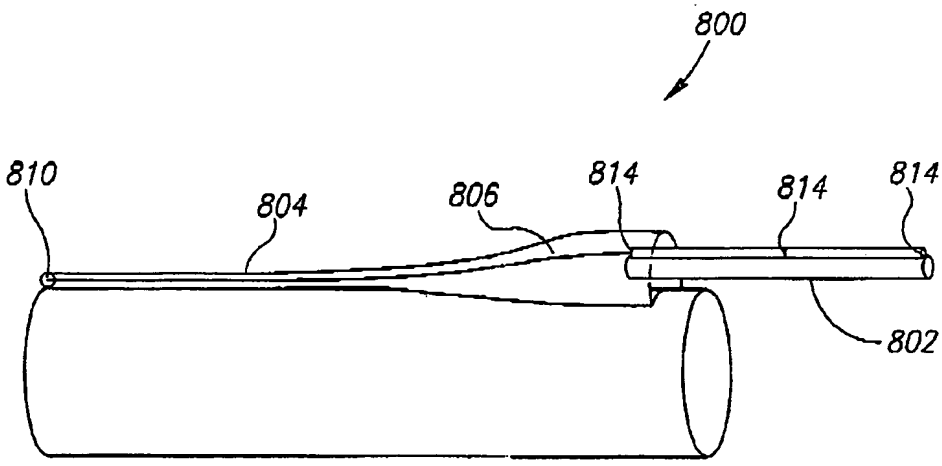
FIG.8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802

FIG.9

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/025238

International filing date: 04 August 2004 (04.08.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/491,971
Filing date: 04 August 2003 (04.08.2003)

Date of receipt at the International Bureau: 16 September 2004 (16.09.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

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Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse